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Draft Document

**FRAMEWORK FOR A MUTUAL ACCEPTANCE ARRANGEMENT
ON OIML TYPE EVALUATIONS**

OIML TC3/SC5 Secretariat: U.S.A. and BIML

Collaborating members:

Participating: Australia, Austria, Belgium, Bulgaria,
Brazil, China, Cuba, Czech Republic, Denmark, Finland,
France, Germany, Japan, Republic of Korea, Netherlands,
Poland, Romania, Russia, Slovenia, South Africa, Sweden
Switzerland, United Kingdom, U.S.A.

Observing: Canada, Hungary, Indonesia, Israel,
Norway, Slovakia, Yugoslavia

Liaison: CECIP, IAF, IEC, ILAC, ISO

EXPLANATORY NOTE

In December 1997, the U.S. member of CIML received a request from the Chair of the National Conference on Weights and Measures (NCWM) in the U.S.A. to organize a meeting of representatives of selected OIML Member states. The objective of the meeting would be to discuss the principles of mutual recognition of test data with associated certificates for type (pattern) approval. The NCWM has a mutual recognition agreement with Canada with regard to the mutual recognition of test data in national type approvals. It also had already had discussions with the U.K. (NWML) and the Netherlands (NMI) since about 1995 regarding mutual agreements of accepting test data for pattern approvals based on OIML requirements.

This initiative was undertaken for the purpose of contributing to the OIML efforts toward establishing mutual confidence globally in legal metrology activities. In particular, it would contribute to the U.S. efforts, as Secretariat of OIML TC3 “Metrological Control,” with regard to revising OIML Document 13 “Guidelines for bilateral or multilateral arrangements on the recognition of test results, pattern approvals, and verifications.” It also would complement the work of the task group on “Accreditation as Applied to Legal Metrology Activities” (for establishing mutual confidence) established by the CIML Presidential Council in 1997.

In response to the NCWM’s request, the U.S. member of CIML invited representatives of some OIML member states to participate in a meeting at the U.S. National Institute of Standards and Technology (NIST) from April 15-17, 1998. The subject of the meeting would be a discussion of proposal for a “Mutual Agreement for the Utilization of Pattern Approval Certificates and Associated Test Reports in National Pattern Approval Programs.” Australia, Canada, China, France, Germany, Japan, Netherlands, Russia, United Kingdom, and the U.S.A and the Director of the International Bureau of Legal Metrology (BIML) were invited. All invited attended except Russia that, nevertheless, provided input for the discussions by correspondence.

A first draft on “Mutual Acceptance Agreement on OIML Pattern Evaluations” was presented by the convener (S. Chappell, CIML Member for the U.S.A.) to the ad hoc task group at that meeting. A second draft was prepared by the Secretariat on the basis of views expressed at the meeting and distributed to all participants for comment in May 1998. A third draft was prepared and distributed on the basis of comments received on the second draft and editorial changes by the Secretariat. It was subsequently discussed at a meeting of the task group of the CIML Presidential Council on “Accreditation as Applied to Legal Metrology Activities” held at BIML on February 17 - 18, 1999. Representatives of Australia, France, Germany, Japan, Netherlands, Russia, United Kingdom, B. Athané of BIML, and the U.S.A participated in that meeting. Canada sent comments on the third draft by correspondence.

At the February 1999 meeting, the convener was requested to arrange a subsequent meeting and make a proposal for a permanent forum for this work in response to a recommendation by S. Bennett (CIML member for the U.K.) at the 33rd CIML meeting in October 1998. The Secretariat proposed that the work be included in a technical subcommittee (SC) 5 “Conformity Assessment” under OIML TC3 “Metrological Control.” This proposal was distributed to participating members of OIML TC3 for comment and vote along with a 4th draft “Mutual Agreement” prepared in consideration of comments by the ad hoc task group on the 3rd draft.

An International Working Group meeting of OIML TC3 “Metrological Control” was held in Paris, France from June 1 - 3, 1999. Forty persons attended the meeting representing 19 OIML Member states, one OIML Corresponding member state, the OIML Development Council, and two liaison organizations including BIML. The purpose of the meeting was to review the work program of TC3 and establish a new subcommittee TC3/SC5 “Conformity Assessment” that would include as projects the Document on the “OIML Certificate System for Measuring Instruments” and the draft Document on the “Mutual Acceptance Agreement” (MAA). It was agreed at the meeting and subsequently approved by CIML to establish TC3/SC5 with the Secretariat being shared by the U.S.A. and BIML. At this meeting the 4th draft Document on the MAA was reviewed clause by clause, and many changes were agreed upon. It was also agreed to develop supplementary documents to facilitate implementing any subsequent agreements. Such documents would be interpretations of ISO/IEC guides and standards that address the requirements for the bodies involved in type evaluations. The bodies covered would be the laboratories that conduct inspections and tests and prepare test reports and the issuing authorities that review the test reports and make a decision as to whether to issue a certificate of conformance based on the test reports. Requirements for assessment of the competence of these bodies would also need to be considered.

A 5th draft Document on the MAA was prepared on the basis of the comments received on the 4th draft that was distributed in December 1999 for comment and vote to Participants and for comment by Observers of OIML TC3/SC5. The results of that consultation were as follows: Austria – yes, comments; Belgium – yes, no comments; Bulgaria – yes, comments; China – yes, no comments; Czech Republic – no, comments; Denmark – no, comments; France – no, comments; Germany – no, comments; Japan – yes, comments; Netherlands – no, comments; Poland – yes, comments; Russia – yes, no comments; Sweden – no, comments; Switzerland – no, comments; United Kingdom – no, comments; and the U.S.A – yes.

A 6th draft MAA was prepared by the Secretariat based on the comments received on the 5th draft. Also distributed separately by the Secretariat were interpretation Documents prepared by G. Lagauterie of France on the application of ISO 17025 “General requirements for competence of calibration and testing laboratories” and ISO/IEC Guide 65 “General requirements for bodies operating product certification systems.” Also distributed for comment was an OIML draft Document on “OIML procedure for review of laboratories to enable mutual acceptance of test results and OIML certificates” prepared by G.H. Engler of the Netherlands.

An International Working Group meeting of OIML TC3/SC5 was held in Paris, France from June 27 - 29, 2000. Thirty-six persons attended the meeting representing the following: 15 OIML member states that collaborate in the work, one corresponding OIML member state, the OIML Development Council, and two liaison organizations including the European Weighing Manufacturers Association (CECIP) and BIML. The purpose of the meeting was to review the 6th draft MAA, the interpretation (application) documents, and the draft Document on “OIML procedure for review of laboratories....” The 6th draft was reviewed clause by clause and several editorial changes and corrections were adopted. After substantial discussions, it was agreed that the Secretariat would prepare a 7th draft MAA Document that would include “self-assessment” as a means for determining the competence of participants in a “declaration of mutual confidence.” The results of accreditation or self-assessment would be peer reviewed by expert representatives

of participants. Follow-up requests for information or visits of experts to review the activities of potential participants may be required if necessary and justifiable. It was further agreed that the Secretariat would prepare checklists for use in assessments of participating testing laboratories and issuing authorities according to the requirements of ISO/IEC 17025 and Guide 65 respectively. The work to develop the “application” documents would continue.

The Secretariat provided a report on the status of this project during a round table discussion of “Mutual Recognition” at the 11th International Conference of Legal Metrology in London in October 2000 to CIML members. It was decided that the Presidential Council would consider the direction of this project at its next meeting in February 2001 and provide recommendations for its future to the Secretariat.

A 7th draft MAA was developed taking into consideration the comments received on the 6th draft and the decisions of the June 2000 meeting of the International Working group of OIML TC3/SC5. This draft was distributed for comment and vote in October 2000. The results of that consultation were as follows: Australia – no, comments; Austria – yes, comments; Canada – comments; China – yes, comments; Czech Republic – yes, comments; Denmark – no, comments; Germany – abstain, comments; Japan – yes, comments; Republic of Korea – comments; Monaco – comments; Netherlands – no, comments; Norway – comments; Poland – yes, comments; Romania – abstain, no comments; Sweden – no, no comments; Switzerland – yes, comments; United Kingdom – no, comments; and the U.S.A – yes.

At its meeting in February 2001, the Presidential Council decided that the means of assessing competence of potential participants in the MAA should be based on either accreditation or peer assessment. The 8th CD MAA was developed taking into consideration the comments received on the 7th draft and the discussions and decisions of the CIML Presidential Council at its meeting in February 2001. The process of determining competence by self-assessment introduced in the 7th draft was deleted. The Secretariat included in the 8th draft MAA a proposed third way of establishing competence for testing laboratories that have successfully completed a documented intercomparison testing of the relevant category of measuring instruments or devices according to the requirements of OIML Recommendations with other participants. In such cases, the testing laboratories would not be required to undergo an on-site assessment of competence. This proposal was discussed with the CIML President and the Appointed Director of BIML who expressed positive views.

The 8th CD was distributed for comment and vote in August 2001. The Secretariat also provided a presentation to CIML Members on that draft at the 36th CIML meeting in Moscow in September 2001. The results of that consultation were as follows: Australia – no, comments; Austria – yes, comments; Belgium – yes, comments; Brazil – yes, comments; Bulgaria – yes, no comments; China – yes, comments; Czech Republic – yes, no comments; Denmark – no, comments; Finland – no, comments; France – no, comments; Germany – no, comments; Japan – yes, no comments; Republic of Korea – yes, no comments; Netherlands – yes, comments; Poland – yes, no comments; Romania – yes, no comments; Russia – yes, no comments; South Africa – yes, comments; Sweden – no, comments; Switzerland – no, comments; United Kingdom – no, comments; and the U.S.A – yes.

The 9th CD MAA was developed taking into consideration the comments received on the 8th CD. In particular, the laboratory intercomparison option for testing laboratories was changed from being a stand-alone option for demonstrating competence to being included as part of the peer-review option.

The 9th was distributed for comment and vote in February 2002. The results of that consultation were as follows: Australia – yes, comments; Austria – no, comments; Belgium – yes, no comments; Brazil – yes, no comments; Bulgaria – yes, no comments; China – yes, no comments; Czech Republic – yes, comments; Cuba - yes, no comments; Denmark – no, comments; Finland – no, comments; France – no, comments; Germany – no, comments; Japan – yes, comments; Republic of Korea – yes, no comments; Netherlands – yes, comments; Poland – yes, no comments; Romania – yes, no comments; Russia – yes, no comments; South Africa – yes, comments; Sweden – no, comments; Switzerland – no, comments; United Kingdom – abstain, comments; and the U.S.A – yes.

After discussions with the Secretariat at the 37th CIML meeting, the United Kingdom changed its vote from “abstain” to “yes”, thus providing two-thirds approval of the 9th CD MAA by P-members of OIML TC3/SC5 and permitting the MAA to become a Draft Document for CIML review and vote. It was decided to first conduct an unofficial preliminary vote to try and obtain further consensus before an official vote by the CIML. The 1st Draft Document was developed taking into consideration the comments received on the 9th CD.

In the 1st Draft Document circulated to the CIML for preliminary vote, the concept of an “Associate” was added to clarify the role of OIML Corresponding Members in the MAA. This was done to provide opportunity for Corresponding Members to be aware of and obtain some of the information generated by the committees on participation review. Also added was the possibility of an OIML Issuing Authority issuing an OIML Certificate along with an authenticating letter validating the test report. Only 30 of the 58 CIML members returned ballots for the preliminary vote: 24 members voted “yes”, 4 members voted “no”, and 2 members abstained. Numerous comments were submitted, none of them differing significantly from comments that had been received on the 9th CD.

The 1st Draft Document (along with comments) was discussed in detail at a Workshop held at the Maison de la Chimie in Paris on June 2 and 3, 2003. Many key issues were identified and discussed, including whether there is a need for an MAA, clarification of the Scope (including participants), allowed methods of demonstrating competence of issuing authorities and testing laboratories, costs and their allotments, allowance of additional requirements beyond those in OIML Recommendations, potential conflict with the European Measuring Instrument Directive (MID), identifying who makes decisions and votes on MAA matters, the status and purpose of the Checklists document, and whether full ISO documents should instead be used. This 2nd Draft Document reflects the outcome of these discussions and considerations.

CONTENTS

	Page No.
0 Introduction	1
1 Scope	2
2 Objectives of the mutual acceptance arrangement	3
3 Terminology	3
4 Requirements for establishing a declaration of mutual confidence	7
4.1 Instruments included	7
4.2 Number of declarations per instrument category	7
4.3 Record of a declaration	7
4.4 Types of participants	7
4.5 Minimum number of issuing authorities	8
4.6 Assessments of issuing authorities and testing laboratories	8
4.7 Supplementary means for testing laboratories to demonstrate competence	9
4.8 Notification of decisions	10
4.9 Application for participation	10
4.10 Reviewing participation	11
4.11 Approval of participation	12
4.12 Record of participation	12
5 Requirements for implementing a declaration of mutual confidence	13
5.1 Commitment of participants	13
5.2 Information for customers	13
5.3 Additional, not substantially different requirements	14
5.4 Preparation of the test report	14
5.5 Transmission and use of a test report	15
5.6 Consultations on a test report	15
5.7 Responsibility for the test report	15
5.8 Collaborations of participants	15
6 Role of the BIML	15
7 Resolution of complaints and disputes	16
8 Initiation, maintenance and termination	17
9 Amendment	18
10 Revision	18
References	19

Annex A	Format for a Declaration of Mutual Confidence.....	20
A.1	Measuring instrument or device category covered	20
A.2	Additional, not substantially different requirements.....	21
A.3	Means used to establishing mutual confidence in the competence.....	21
A.4	Identity and signature of participants.....	22
A.5	BIML receipt.....	22
Annex B	Basic Means of Establishing Mutual Confidence by Accreditation or Peer Assessment	23
B.1	Introduction.....	23
B.2	ISO/IEC 17025 as applicable to testing laboratories	23
B.3	ISO/IEC Guide 65 as applicable to issuing authorities.....	27
Annex C	General Format: Questionnaire “National Capabilities for Type Testing”.....	31

0 Introduction

- 0.1 The International Organization of Legal Metrology (OIML) was established in 1955 as an intergovernmental body (treaty) dedicated to harmonizing the national metrology regulations of its member states. Its administrative headquarters is the International Bureau of Legal Metrology (BIML) located in Paris, France. The International Committee of Legal Metrology (CIML), which is comprised of one member representing each Member State, provides oversight and supervision of the technical activities of the OIML.
- 0.2 Technical committees within the OIML develop Recommendations for specific categories of measuring instruments. OIML Recommendations provide the characteristics and performance requirements for measuring instruments and include the examination and test procedures used to evaluate the performance requirements and a format of the test report for reporting the results of a type evaluation. After achieving a consensus within the originating technical committee and CIML, an OIML Recommendation is approved by the CIML for publication.
- 0.3 In 1991, the “OIML Certificate System for Measuring Instruments” (OIML Certificate System) was introduced. It provides a means by which an issuing authority designated by a participating Member State may issue test reports validated by an OIML certificate. No obligation exists for OIML member states to accept or recognize such test reports and associated OIML certificates. These test reports with certificates, however, may be presented by their owners (e.g. manufacturers) as evidence of conformity with the requirements of the relevant OIML Recommendation for the purposes of applying for type approval or initial verification in another OIML Member State.
- 0.4 A consensus has developed globally among legal metrologists that an effective means for removing and avoiding technical barriers to trade for measuring instruments may be achieved through harmonizing the performance requirements for measuring instruments under legal metrological control and mutual agreements to accept and utilize type evaluation results. For this purpose, it was recognized that a mutual arrangement could be established among national bodies responsible for the legal metrological control of such instruments.

- 0.5 After extensive discussions, representatives of interested OIML Member States concluded that OIML Recommendations and the OIML Certificate System could provide the basis for developing a voluntary mutual arrangement among participants to accept and utilize reports of type evaluation that were reviewed and transmitted by participating issuing authorities. The mutual arrangement would be applied in the national and regional type approval or recognition programs of participating states. An important prerequisite for establishing such an arrangement would be achieving mutual confidence in the testing and certification capabilities among participants.

1 Scope

- 1.1 This mutual acceptance arrangement (MAA) establishes the rules for a voluntary framework whereby participants within OIML Member States and Corresponding Members accept and utilize test reports, as defined in 3.8, when validated by issuance of an OIML Certificate, for type approval or recognition in their relevant national or regional metrological control programs, and/or for issuing subsequent OIML Certificates. The MAA covers all items in the OIML test report for which detailed procedures are prescribed in the Recommendation. OIML Issuing Authorities and the Testing Laboratory or Laboratories that they utilize or supervise are all subject to evaluation of competence under this Arrangement.
- 1.2 The implementation of this MAA is through the establishment of a separate “declaration of mutual confidence” for each category of instruments. Procedures are provided for establishing, operating, and terminating a declaration of mutual confidence and for participants to appeal and resolve issues concerning their participation.
- 1.3 A declaration of mutual confidence shall not be legally binding; however, participants shall have an obligation to cooperate in the implementation, improvement, and clarification of all provisions according to this mutual arrangement.
- 1.4 Issuing authorities and/or national responsible bodies of OIML Corresponding Members may voluntarily take part in a “declaration of mutual confidence” as Associates by indicating in writing their willingness to accept and utilize test reports. Associates do not participate in the committees on participation review.

- 2 Objectives of the mutual acceptance arrangement
 - 2.1 To establish rules and procedures for fostering mutual confidence among participating OIML member states in the results of type evaluations that indicate the conformity of measuring instruments, under legal metrological control, to OIML metrological and technical requirements and, when included, any agreed upon additional requirements.
 - 2.2 To promote the global harmonization, uniform interpretation, and implementation of legal metrological requirements for measuring instruments.
 - 2.3 To promote efficiency in time and cost of national type evaluations and approvals or recognition of measuring instruments under legal metrological control while achieving and maintaining confidence in the results in support of facilitating global trade of individual instruments.
- 3 Terminology

Note: A reference is provided in parenthesis after the definition of the term to indicate the applicable definition or comparable definition in references [1], [2] or [3].

 - 3.1 OIML Recommendation - publication addressing categories of measuring instruments or devices that includes metrological and technical performance requirements, a test procedure for evaluating conformity to the requirements, and a format of the test report.
 - 3.2 Category of instruments – identification or classification of instruments according to characteristics that may include the measured quantity, the measuring range, and the principle or method of measurement.
 - 3.3 Type of a measuring instrument - definite model of the category of instruments to which it conforms.
 - 3.4 Type evaluation - systematic examination and testing of the performance of one or more specimens of an identified type of measuring instruments against documented requirements, the results of which are contained in an evaluation report, in order to determine whether the type may be approved. (VIML – 2.5)

- 3.5 Type approval - decision of legal relevance, based on the evaluation report, that the type of a measuring instrument complies with the relevant statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time. (VIML – 2.6)
- 3.6 Conformity - fulfillment by the measuring instrument type of specified requirements. (ISO/IEC Guide 2 – 12.1)
- 3.7 OIML Certificate of conformity - document issued by an OIML issuing authority indicating that the identified measuring instrument type is in conformity with the requirements of the applicable OIML Recommendation.
- 3.8 OIML test report – report which accompanies an OIML Certificate under the OIML Certificate System

P1: OIML Certificate System for measuring instruments, edition 2003 - 2.12:

Report, prepared according to the Test Report Format specified in the relevant Recommendation, that gives the results of the examinations and testing carried out during type evaluation on an identified sample or samples of a given type and a conclusion as to whether the sample or samples meet the specified requirements.

- 3.9 Test report – report comprised of the OIML test report, and, when applicable, a complementary test report containing test results for any agreed upon additional requirements.

Note 1: The test report gives the results of the examinations and testing carried out during type evaluation on an identified sample or samples of a given type and a conclusion as to whether the sample(s) meet the specified requirements.

Note 2: The test report constitutes the evaluation report referred to in 3.4.

Note 3: The complementary test report may be validated by a letter from the OIML Issuing Authority.

- 3.10 National Issuing Authority - certifying body or person in an OIML member state that is responsible for national type approval and that issues certificates of conformity for

specific categories of measuring instruments on the basis of examination and testing under its own control.

- 3.11 OIML Issuing Authority – certifying body in an OIML Member State, designated by its CIML Member, that issues OIML Certificates of conformity for a particular category of instruments.

Note: The OIML Issuing Authority may or may not be the same organization as the national issuing authority whose responsibilities are governed by national regulations. When the term “issuing authority” is used in this document without a modifier, both OIML issuing authority and National issuing authority are assumed.

- 3.12 National responsible body - organization within an OIML member state that does not conduct type evaluation but is responsible for the metrological control of measuring instruments including the approval or recognition of specific types of measuring instruments for national use.
- 3.13 Testing laboratory - the principal laboratory including any necessary specialized laboratory or laboratories designated by the issuing authority to carry out examination and testing of a sample or samples of a measuring instrument submitted for type evaluation, with the principal laboratory assuming responsibility for the evaluation results reported.

See Note under 3.11.

- 3.14 Testing – the act of carrying out technical operations that consists of a determination of the metrological and technical characteristics of an instrument according to specified procedures. (ISO/IEC Guide 2 – 13.1)
- 3.15 Examination - official visual inspection of an instrument or device and relevant documentation to assure that some specified requirements are met.
- 3.16 Mutual acceptance arrangement – framework agreement that commits participants to accept and utilize test reports issued by other participants under a particular DoMC, after having established mutual confidence among them through assessment of competence, and to assume any legal responsibility once such reports have been accepted.

- 3.17 Declaration of mutual confidence (DoMC)—attestation by participants that they have achieved a voluntary mutual arrangement with regard to type evaluation to accept and utilize test reports, which include results of examinations and testing, issued by other participants for a specified category of measuring instruments.
- 3.18 Participant – issuing authority or national responsible body of an OIML member state that accedes to a declaration of mutual confidence.
- 3.19 Associate – National issuing authority and/or national responsible body of an OIML Corresponding Member that voluntarily takes part in a “declaration of mutual confidence” by indicating in writing its willingness to accept and utilize test reports.

Note: Associates receive information from, but do not participate in, the committee on participation review.

- 3.20 Conformity assessment - any activity concerned with determining directly or indirectly that relevant requirements are fulfilled. (ISO/IEC Guide 2 – 12.2)
- 3.21 Accreditation - procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (ISO/IEC Guide 2 – 12.11)
- 3.22 Peer assessment - procedure by which one or more agreed-upon legal metrology experts assess, against specified requirements, on site, the competence of the testing laboratory or laboratories designated by a participating issuing authority in the category of measuring instruments covered in a declaration of mutual confidence.
- 3.23 Internal audit – a systematic examination against specified requirements by personnel, not being directly responsible for the activity, to determine whether activities related to an agreed arrangement are implemented effectively and are suitable to achieve stated objectives.
- 3.24 Customer – manufacturer and/or an authorized representative who submits an application for type evaluation of a measuring instrument to an issuing authority participating in a Declaration of Mutual Confidence in order to receive a test report and OIML Certificate for that instrument type

3.25 Applicant – issuing authority or national responsible body that applies to be a participant in a particular Declaration of Mutual Confidence

4 Requirements for Establishing a Declaration of Mutual Confidence

4.1 **Instruments included.** Only those measuring instruments that are a part of the OIML Certificate System may be specified in a declaration of mutual confidence under this arrangement.

4.2 **Number of declarations per instrument category.** Only one declaration of mutual confidence shall exist for each category of instruments; that is, one that encompasses all or some of the applicable instruments or devices covered by an OIML Recommendation. The format for establishing a declaration of mutual confidence is given in Annex A.

4.3 **Record of a declaration.** The specific category of measuring instruments that are covered by a declaration of mutual confidence shall be recorded according to the format in A.1. A participant shall indicate in A.1 which additional tests specified in A.2 they have successfully demonstrated their competence to perform.

4.4 **Types of participants.** A participant in a declaration of mutual confidence may be:

- a) an issuing authority that issues complete OIML test reports that are validated by an OIML certificate issued by the OIML issuing authority in that country, which may or may not be the same body, and that accepts and utilizes test reports issued by other participants in that DoMC

Note: This type of participant may include one OIML issuing authority and one or more national issuing authorities per Member State.

- b) a national responsible body or an issuing authority that does not issue OIML test reports under a particular DoMC, but accepts and utilizes test reports issued by participants mentioned in a)

Note: For those OIML Issuing Authorities that choose to participate and are not National Issuing Authorities, then both the OIML Issuing Authority and the National

Issuing Authority shall participate.

4.5 **Minimum number of issuing authorities.** At least two issuing authorities as described in 4.4 (a), preferably from different regions, shall be required to establish a declaration of mutual confidence.

4.6 **Assessments of issuing authorities and testing laboratories.** Prior to establishing a declaration of mutual confidence for a specific category of instruments:

- The committee on participation review shall identify the list of tests for which detailed procedures are prescribed in the appropriate Recommendation, and the list of additional tests to be optionally performed by the participants. These lists will be used to establish the scope of assessment of competences of the issuing authorities and testing laboratories. OIML TCs/SCs should be invited to consider removing or making more explicit the examination procedures or other inadequately-defined procedures in the appropriate Recommendations.
- The issuing authorities as described in 4.4 (a) and all of the testing laboratories that they use in conjunction with a particular DoMC shall be assessed either by accreditation or peer assessment using criteria that comply with ISO/IEC 17025 for the scope of assessment as determined above.
- The OIML issuing authorities that validate the test reports shall conduct internal audits using criteria that comply with ISO/IEC Guide 65. If the OIML issuing authority is the same as the issuing authority in the second bullet above, it shall in addition be assessed as required in the second bullet.

The costs for carrying out the assessments of the issuing authorities and testing laboratories is to be borne by the body that is being assessed.

4.6.1 The accreditation body that carries out an assessment of the laboratory or laboratories of an applicant for participation in a declaration of mutual confidence shall participate in a mutual recognition agreement among accrediting bodies in the participating Member states or within regions that include the intended participants in a proposed or existing declaration of mutual confidence as, for example, participation in the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement. In

accrediting a testing laboratory, the assessment team shall include at least one member who is an expert in legal metrology for the category of instruments or devices covered. The “committee on participation review” shall be consulted regarding the qualifications of the expert selected.

4.6.2 The peer assessments shall be carried out by a team of experts, including at least one legal metrology expert in the category of instruments covered and at least one expert knowledgeable in the requirements of "quality systems." Such expert or experts shall be appointed and mutually agreed upon by the relevant “committee on participation review.” (See 4.10.) A list of qualified persons for peer assessment for a specific category of instruments shall be maintained by BIML according to recommendations and criteria approved by participants. An expert that participates in conducting a peer assessment shall not be a member of the committee on participation review.

4.6.3 The assessment requirements according to ISO/IEC Guide 65 for issuing authorities and of the assessment requirements according to ISO/IEC 17025 for testing laboratories are briefly outlined in Annex B. “Checklists” for such internal audits and assessments are given in the Draft OIML Document on “Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations” [8]. Procedures for peer assessment should be consistent with those provided in ISO/IEC CD 17040 “General requirements for peer assessment of conformity assessment bodies.”

Note: The criteria for an accreditation, a peer assessment, or an internal audit should be consistent with any approved, relevant OIML documents on the application of relevant ISO/IEC standards and guides.

4.6.4 The means used for establishing mutual confidence shall be indicated in A.3.

4.7 **Supplementary means for testing laboratories to demonstrate competence.** The means of establishing and maintaining confidence in competence of testing laboratories as specified in 4.6 may be supplemented by some, but not necessarily all, of the following actions:

- exchange of information regarding national capability for testing,
- exchange of information on training of issuing authority and testing laboratory personnel, and
- exchange of test data.

Any supplementary means used for establishing mutual confidence shall be indicated in A.3.

- 4.8 **Notification of decisions.** After a decision to establish a declaration of mutual confidence, potential participants shall notify BIML through their CIML members of their intention. In turn, BIML shall inform all other OIML member states of this intention so that other Member states may also consider participating.
- 4.9 **Application for participation.** Application for participation in a declaration of mutual confidence shall be submitted to the BIML and shall be accompanied by the following information:
- 4.9.1 For an issuing authority that intends to review and transmit test reports in a declaration of mutual confidence:
- the applicant shall submit for information the report of the results of the most recent internal audit according to the “Checklists” [8] for ISO/IEC Guide 65 or, if available, a certificate of accreditation covering the scope of the declaration of mutual confidence. A completed questionnaire must also be provided on “National Capabilities for Type Testing” for which a generic form is provided in Annex C;
 - for all testing laboratories to be utilized by the applicant that use accreditation as the means for demonstrating competence, the applicant shall submit a certificate of accreditation for the testing laboratories that includes the scope of the declaration of mutual confidence and enough information that an assessment of the legal metrology aspects of the accreditation can be determined. The composition and qualifications of the assessment team must be provided.
 - for all testing laboratories to be utilized by the applicant using peer evaluation as the means for demonstrating competence, the applicant shall submit the reports of the results of the most recent internal audits and, if available, a certificate of accreditation covering part of the scope of the declaration of mutual confidence or other evidence of competence. These reports shall be according to the “Checklists” [8] for ISO/IEC 17025, and shall include enough information that an assessment of the legal metrology aspects of the accreditation can be determined.

- a report may be submitted on the results of the participation in intercomparisons, if any, of relevant testing by any of the designated testing laboratories;
- the proposed expert to serve on the committee on participation review shall be identified by the CIML Member and agree to participate in the work of the committee.

4.9.2 For all applicants in a declaration of mutual confidence:

- if additional evaluations are required in the regulations of the applicant's country, they shall be clearly identified or referenced along with the associated test methods and test report format, if required, in a completed table as given in A.2 (see also 5.3);
- the proposed expert to serve on the committee on participation review shall be identified by the CIML Member.

4.10 **Reviewing participation.** An “committee on participation review” shall be established for the purpose of reviewing the documentation submitted by potential participants, of establishing the scopes of peer assessment when necessary, of establishing lists of experts for conducting peer assessments and participating in accreditations, of preparing reports on the qualifications of potential participants, and for any other purpose required for establishing, expanding, and maintaining the appropriate participation in a declaration of mutual confidence. It shall be open to one expert from each OIML Member State, appointed by the CIML member to represent all of the participants from that Member State, in each established declaration of mutual confidence or representing each potential participant in a declaration of mutual confidence being established.

4.10.1 For an Issuing Authority as described in 4.4 (a) that applies for participation in a declaration of mutual confidence, the committee shall carry out the following tasks:

- review the information submitted in the application;
- accept without further assessment the valid report on the accreditation of a testing laboratory within the scope of the declaration of mutual confidence;
- decide, based on the internal audit report (Checklist), on the scope of the necessary peer assessment of a testing laboratory of an applicant that has not been accredited;
- select, when necessary, the expert or experts that will conduct a peer assessment of the testing laboratory;

- prepare a report, based on all information received including peer assessments when conducted, on the competence of an applicant for distribution to all participants and other potential participants in a declaration of mutual confidence to be used for a decision on participation; and
- review the requirements for a customer to apply for national type evaluation and approval that shall be consistent with the requirements of Clause 3.1 of the OIML P1 "OIML Certificate System for measuring instruments" [1].

4.10.2 For a potential participant that intends only to accept and utilize test reports, and for an Associate, the committee shall review the requirements for a customer to apply for national type evaluation and approval or recognition. Application requirements shall be consistent with the requirements of Clause 3.1 of the OIML P1 "OIML Certificate System for measuring instruments" [1].

4.11 **Approval of participation**

- When a DoMC is first being established, all potential participants shall independently review the reports on all other potential participants prepared by the committee on participation review, and all other potential participants shall independently agree that each potential participant meets the requirements in order that it be accepted as a participant. The potential participants shall originally submit their findings to the BIML representative on the committee, who will transmit all findings to the others only after all findings have first been submitted.
- Once a DoMC is established, all participants shall independently review the report on a potential participant prepared by the committee on participation review, and all participants must agree that the potential participant meets the requirements in order that it be accepted as a participant.

An appeal of a decision is covered in clause 7.

4.12 **Record of participation.** After establishing mutual confidence, the accepted Issuing Authorities and National Responsible Bodies shall sign as participants and, thereby, execute a declaration of mutual confidence, according to the format contained in A.4, that

is then placed on record with the BIML. The CIML Member or other governmental official may sign to confirm the participation of the indicated OIML Member State.

5 Requirements for Implementing a Declaration of Mutual Confidence

5.1 **Commitment of participants.** Participants in a declaration of mutual confidence shall commit their participation according to A.4. Each participant shall agree to implement reciprocity with regard to all other participants in accepting and utilizing or recognizing the test reports prepared according to the relevant OIML Recommendation and any additional test requirements and reviewed and transmitted by other participants.

5.2 **Information for customers.** A participant as described in 4.4 (a) shall provide the following documented information to potential customers (instrument manufacturers or their representatives):

- the procedures for a manufacturer or an authorized representative of a measuring instrument or device to apply for a test report prepared according to the requirements for type evaluation of the category of measuring instruments covered in the declaration of mutual confidence;
- the necessary information and documentation that a manufacturer or an authorized representative shall submit regarding identifying the measuring instrument type to be evaluated;
- the identity of the testing laboratory or laboratories that will carry out the examination and testing;
- the extent of type evaluation that will be conducted;
- the approximate fees and time schedule required for the preparation of test reports; and
- the identity of participating OIML Member states that have agreed to accept and utilize the test reports in their national or regional metrological control programs and their requirements for type approval or recognition.

Note: The appropriate requirements of Clause 3 "Processing of a Certificate" of the OIML P1 "OIML Certificate System for measuring instruments" [1] should be followed, especially 3.1.2 regarding the required documentation identifying the instrument type submitted in the application for type evaluation.

5.3 **Additional requirements and evaluations.** In order to issue a national certificate of conformity on the basis of a test report received from another participant, the issuing

authority may be required by national or regional laws and regulations to perform additional evaluations to those required in the relevant OIML Recommendation.

A participant requiring any additional type evaluations shall clearly identify them with an explanation and justification and also reference them along with any necessary additional associated test methods and test report format in A.2. Such references shall be updated promptly after any change in these requirements.

These additional evaluations shall be included in the scope of the DoMC when accepted by the committee. Additional evaluations may be proposed, in particular for the following cases:

- testing at severity levels different than those specified in the OIML Recommendation (e.g., testing to different EMC severity levels);
- the OIML Recommendation does not provide adequately detailed testing procedures (e.g., software testing);
- the national regulation contains testing and other requirements for characteristics not covered by the OIML Recommendation (e.g., tests for resistance to sand or zinc in water for water meters).

Other participants may choose to carry out these evaluations, in addition to the tests within the corresponding OIML Recommendation, in order to provide customers “one-stop” testing. Performing these additional tests is optional for each participant.

5.4 **Preparation of the test report.** The test report shall be prepared by either the principal testing laboratory or the responsible issuing authority. If prepared by the principal testing laboratory, it shall be reviewed by the responsible issuing authority. It shall be completed according to the format of the test report of the applicable OIML Recommendation and shall clearly identify the instrument evaluated and those responsible for carrying out type evaluation, especially the principal laboratory and any specialized laboratories utilized. For those participants who choose to do so, the test report may include the results of evaluations carried out at the request of the customer and according to the additional requirements of some participants.

5.5 **Transmission and use of a test report.**

- 5.5.1 The issuing authority shall transmit the test report to a customer in the following ways:
- with an OIML Certificate of Conformity, prepared according to the rules established in OIML P1, and
 - with a letter validating the complementary test report, if any.
- 5.5.2 The customer that receives the test report with certificate and letter, if obtained, then may use it (them) in an application for national or regional type evaluation in another country.
- 5.5.3 The Issuing Authority shall send a copy of each Certificate and letter it issues to the BIML for registration according to the rules in 4.1 of P1.
- 5.6 **Consultations on a test report.** In the event that questions arise during the review of a test report received, a participant shall consult the participant responsible for transmitting the test report for clarification of the matter and take any necessary further actions that may be required. In all cases, the customer shall be informed clearly of the details of any such consultations.
- 5.7 **Responsibility for the test report.** A participant that accepts a test report under the terms of the MAA and utilizes it to issue a national or OIML certificate of conformance shall also assume responsibility for the test report according to national regulation.
- 5.8 **Collaborations of participants.** Representatives of each participant in a declaration of mutual confidence shall collaborate, as applicable, in the following efforts:
- to mutually accept and utilize test reports as received;
 - to make non-confidential information pertaining to all type evaluations available upon request, or as agreed upon, to other participants;
 - to maintain the confidentiality of proprietary information;
 - to monitor the capability and competence of their testing laboratories;
 - to achieve and maintain competence for determining conformity to requirements when reviewing test reports; and
 - to provide active participation in any technical revisions of relevant OIML Recommendations.
6. The Role of the BIML

- 6.1 After being informed, the BIML shall promptly announce a decision to initiate a declaration of mutual confidence. The BIML shall receive the information specified in 4.9 from an OIML Member State, through its CIML member, of its intention to participate in a proposed or an existing declaration of mutual confidence.
- 6.2 The BIML shall assist the committee on participation review in its responsibilities and assume necessary administrative roles in facilitating a declaration of mutual confidence. Administrative fees, approved by the CIML, may be imposed and collected by the BIML to recover costs associated with the various identified tasks assumed. Operational expenses for administering the MAA program are anticipated to be fully covered by the administrative fees and not by the annual contributions of Member States and Corresponding Members' fees.
- 6.3 The BIML shall prepare for CIML members periodic reports indicating the number of certificates issued to customers by Member states that utilized test reports under this arrangement. Each participant in a specific declaration of mutual confidence shall provide the BIML the necessary information as the basis for this report.
- 6.4 The BIML shall be responsible for monitoring and maintaining records of all declarations of mutual confidence and shall also provide, upon request, information on current activities to any interested party in an OIML Member State through its CIML member. Information about the mutual acceptance arrangement shall be published periodically in the OIML Bulletin.
- 7 Resolution of complaints and disputes
 - 7.1 The BIML shall be contacted in the event of a dispute initiated by either a customer regarding a test report or a participant concerning the operational procedures of this framework for a mutual acceptance arrangement. The BIML will also provide, if requested, an interpretation or clarification of the intent of the arrangement.
 - 7.2 An applicant that has not been accepted to participate in a declaration of mutual confidence may appeal that decision.
 - 7.3 The CIML members may represent the participants involved in a dispute and shall attempt to resolve among themselves any issue that might arise. If the participants

affected are unable to resolve an issue, they shall provide a written explanation to the BIML for distribution to the CIML members representing all other participants.

- 7.4 A complaint may be submitted to the BIML with documented and substantiated evidence that a test report was prepared, reviewed, or transmitted by a participant on the basis of incorrect technical conclusions or procedures. The BIML shall notify the owner of the documentation and all other participants in a declaration of mutual confidence of the complaint.
- 7.5 Such unresolved disputes and complaints as indicated in 7.3 and 7.4 may be referred to the CIML Presidium (consisting of the CIML President and two Vice Presidents). The Presidium would consider the matter or refer it for resolution to an ad hoc task group of CIML members consisting of representatives of non-involved participants.
- 7.6 A participant that fails over time to respect the obligations of a declaration of mutual confidence may be excluded from further participation upon a resolution in writing agreed upon by all other participants.
- 8 Initiation, maintenance and termination
- 8.1 Each declaration of mutual confidence established according to Annex A shall become effective on the date that it is recorded by the BIML.
- 8.2 In order to be active in a declaration of mutual confidence, participants shall be required to undergo internal audits and re-assessments of competence according to the following schedule:
- issuing authorities shall produce a report on their internal audits according to "Checklists" [8] or accreditation reports at least once every two years,
 - testing laboratories that are accredited shall undergo surveillance as required by the accreditation body and be re-accredited at least once every four years,
 - testing laboratories that undergo on-site peer assessment shall produce a report on an internal audit according to "Checklists" [8] at least once every two years for surveillance and shall be subject to a peer re-assessment at least once every four years.

- 8.3 The reports shall be submitted to the relevant committee on participation review, that shall review these reports and report to the participants the need for any possible subsequent actions (see 7.6).
- 8.4 A declaration of mutual confidence shall not be legally binding although participants agree to cooperate in its implementation, improvement, and clarification of provisions.
- 8.5 A participant may withdraw from a declaration of mutual confidence upon a written notice to the BIML taking into account all current obligations to customers for type evaluation, and BIML shall in turn notify all other participants. All remaining participants, however, shall accept and utilize or recognize the test reports that were prepared, reviewed, and transmitted by the issuing authority of the participant prior to withdrawal.
- 8.6 OIML TCs/SCs will be invited to develop technical interpretation guides to clarify certain aspects of Recommendations under their responsibility as matters are brought to their attention by participants in the MAA.
- 9 Amendment
- 9.1 A declaration of mutual confidence may be reviewed and amended when necessary to incorporate changes in technical or administrative requirements that do not conflict with this Document. All current participants in a declaration of mutual confidence shall agree upon any specific changes.
- 9.2 The detailed requirements for participation in a declaration of mutual confidence shall be reviewed after an OIML Recommendation on which it is based is revised. After such a review, amendments to a declaration of mutual confidence may be required.
- 10 Revision
- 10.1 A revision of this Document shall be the responsibility of the Secretariat and International Working Group for OIML TC3/SC5.
- 10.2 This Document and its revisions shall be approved by the CIML.

References

- [1] OIML P1: “OIML Certificate System for Measuring Instruments” (Second edition 2003)
- [2] OIML “International Vocabulary of Terms in Legal Metrology” (VILM): 2000.
- [3] ISO/IEC Guide 2:1996, Standardization and related activities - General vocabulary.
- [4] ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories.
- [5] ISO/IEC Guide 58:1993, Calibration and testing laboratory accreditation systems - General requirements for operation and recognition.
- [6] ISO/IEC Guide 61:1996, General requirements for assessment and accreditation of certification/registration bodies.
- [7] ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems.
- [8] Draft OIML Document on “Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations,” July 2003.
- [9] ILAC document G10:1996 Harmonized Procedures for Surveillance and Reassessment of Accredited Laboratories.
- [10] ISO/IEC CD 17040: 2001 General requirements for peer assessment of conformity assessment bodies.
- [11] ISO/IEC CD 17000, Conformity Assessment-General Vocabulary

ANNEX A

Format for a Declaration of Mutual Confidence

Relevant OIML Recommendation (4.1, 4.2): _____

Items in Recommendation not covered (1.1): _____

Note: All reference numbers are to clauses in the “Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations”.

A.1 The specific measuring instrument or device category covered (4.3):

State	Issuing Authority	Principal Testing Laboratory	Range of evaluation capability (class, measuring range, etc.*)

* for accredited laboratories, the scope of accreditation (4.9.1).

A.2 Additional requirements, where applicable (5.3):

Note: Use additional pages as required.

State	Name of requirement	Requirements: reference document(s) and applicable clause(s)	Evaluation procedures: document(s) and applicable clause(s) if necessary

A.3 Means used for establishing mutual confidence in the competence of testing laboratories (4.6):

Note: Use additional pages as required.

State	Means of establishing mutual confidence		
	Accreditation	Peer assessment	Supplementary (if carried out, see 4.7)

- A.4 The participants indicated below hereby attest that they have achieved a voluntary mutual arrangement to accept and utilize test reports issued by other participants in their national type approval program for the category of instruments specified in A.1. This declaration of mutual confidence has been established in accordance with the requirements of the OIML Document on “Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations” dated _____.

State	Identity and signature of issuing authority [designated (a) if reviews and transmits test reports and (b) if not] (4.4)	CIML Member or other governmental official (signature optional)	Date

- A.5 BIML Receipt:

Date recorded at BIML: _____ (effective date) Signature: _____ Director, BIML
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ANNEX B

Basic Means of Establishing Mutual Confidence by accreditation or peer assessment

B.1 Introduction

B.1.1 The requirements used for accreditation or peer assessments of competence of testing laboratories shall be consistent with the requirements of ISO/IEC 17025:1999. Issuing authorities shall carry out internal audits of their procedures consistent with the requirements of ISO/IEC Guide 65:1996.

B.1.2 In this Annex, B.2 and B.3 are outlines with specific references to relevant clauses of ISO/IEC 17025:1999 as indicated in parenthesis () and with specific references to relevant clauses of ISO/IEC Guide 65:1996 as indicated in brackets []. Also indicated are specific references to relevant clauses in the OIML publication on the “OIML Certificate System for measuring instruments” (Edition 2003 being published) as indicated by { }.

Note: Details of the specific applications (interpretations) of the ISO/IEC 17025 and ISO/IEC Guide 65 are provided in the Draft OIML Document on “Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations” and may also be available in other, relevant OIML Documents.

B.2 ISO/IEC 17025 as applicable to testing laboratories and OIML issuing authorities, when applicable

B.2.1 Scope (1), [1], {1}

The assessment of a testing laboratory is carried out by either a recognized accreditation body or by peer assessment.

B.2.2 Normative references (2)

OIML Certificate System for Measuring Instruments (Edition 2003 being published)

OIML Recommendations (various, for specific measuring devices)

B.2.3 Terms and definitions (3), [3], {2}

B.2.4 Management requirements {3.3.1}

B.2.4.1 Organization and management (4.1)

The principal testing laboratory shall have adequate test facilities and equipment; competent management, technical, and support personnel; and documented procedures for type evaluation of instruments and devices covered. It shall ensure the confidentiality of information and proprietary rights of customers and shall operate with impartiality and integrity.

B.2.4.2 Quality system (4.2)

The testing laboratory shall establish, implement, and maintain a documented quality system for type evaluations and shall observe good laboratory practice in carrying out tests. It shall regularly assess its performance in accordance to such requirements.

B.2.4.3 Document control (4.3)

The testing laboratory shall establish and maintain procedures to control all documents associated with type evaluations.

B.2.4.4 Request, tender, and contract review (4.4), {3.1, 3.2}

The testing laboratory shall adhere to the procedures for the application for type evaluation established by the issuing authority and shall provide a customer the schedule of required fees in advance.

B.2.4.5 Sub-contracting of tests (4.5), {3.3.4}

The issuing authority may authorize a principal laboratory to sub-contract some specified testing; however, the issuing authority shall ensure the competence of all laboratories utilized through either accreditation or peer assessment of compliance with ISO/IEC 17025. Customers for type evaluation shall be informed in advance of the intention of using a subcontractor for specified tests, and the subcontractor shall be identified accordingly in the test reports. The principal laboratory shall prepare the test report and, therefore, be responsible for all test results.

B.2.4.6 Purchasing services and supplies (4.6),

The testing laboratory shall have policies and procedures for the selection and purchasing of all services and supplies necessary for type evaluations.

B.2.4.7 Services to the client (4.7), {3.2}

The testing laboratory shall provide clarification of all requirements for customers and permit access to monitoring testing under appropriate safeguards.

B.2.4.8 Complaints (4.8), {6.2, 6.4}

The testing laboratory shall follow established procedures for resolving complaints, disputes, and appeals regarding type evaluations and test reports.

B.2.4.9 Control of nonconforming testing (4.9), {6.5}

The testing laboratory shall have procedures for taking action, informing affected parties, and recalling necessary documents when nonconforming testing is identified.

B.2.4.10 Corrective action (4.10), {6.1}

The testing laboratory shall have policies and procedures for taking action to correct and monitor administrative or technical actions that have resulted in giving nonconforming test results.

B.2.4.11 Preventive action (4.11), {6.1}

The testing laboratory shall initiate corrective actions for problems that might cause nonconforming testing as soon as such problems are identified.

B.2.4.12 Records (4.12), {3.3.1}

The testing laboratory shall establish and maintain procedures for identifying, filing, accessing, and disseminating type evaluation test reports.

B.2.4.13 Internal audits (4.13)

The testing laboratory shall conduct periodic internal audits by trained personnel, who are independent of the activity, to verify compliance with all procedures necessary to demonstrate competence in type evaluation testing.

B.2.4.14 Management reviews (4.14)

The management personnel of the testing laboratory shall conduct periodic reviews of the administrative and technical procedures to ensure their continuing suitability and effectiveness and to introduce any necessary improvements and efficiencies.

B.2.5 Technical requirements

B.2.5.1 General (5.1)

B.2.5.2 Personnel (5.2)

The management of the testing laboratory shall ensure that the staff involved in type evaluations is qualified and maintains competence through experience, education, training, and appropriate supervision.

B.2.5.3 Accommodation and environmental conditions (5.3)

The testing laboratory shall have the necessary and appropriate facilities for power, lighting, temperature, and humidity, and other controls necessary to carry out the required type evaluations.

B.2.5.4 Test methods including sampling (5.4), (5.7), {3.3.3}

The testing laboratory shall implement all test methods including sampling as specified in the relevant OIML Recommendation and any referenced supplementary documents.

B.2.5.5 Equipment (5.5)

The testing laboratory shall have all the identified necessary and appropriate equipment for type evaluation testing and shall have documented procedures for the appropriate operation, maintenance, repair, and calibration of the equipment.

B.2.5.6 Measurement traceability (5.6)

The testing laboratory shall acquire and maintain the reference and working physical standards necessary for calibrations and type evaluation testing. The documented calibrations of all physical standards shall be traceable to national standards.

B.2.5.7 Handling and transportation of test items (5.8)

The testing laboratory shall have procedures for the transport, handling, protection, and storage of all samples of instrument types received and evaluated.

B.2.5.8 Assuring the quality of test results (5.9)

The testing laboratory should implement procedures for assuring the quality of test results such as maintaining the quality control of standards, participating in laboratory intercomparisons, and exchanging information and test data.

B.2.5.9 Reporting the results (5.10), {3.4.1}

The testing laboratory shall prepare the report of the type evaluation in accordance with the requirements of format of the test report in the relevant OIML Recommendation and for any additional, not substantially different tests (listed in A.2, for example).

B.3 ISO/IEC Guide 65 as applicable to OIML issuing authorities

B.3.1 Scope [1], {1}

This clause applies to an issuing authority that carries out a certification process for measuring instruments submitted for type evaluation.

B.3.2 Normative references [2]

OIML Certificate System for measuring instruments (Edition 2003)

OIML Recommendations (various, for specific measuring devices)

B.3.3 Terms and definitions [3], {2}

The relevant terms in ISO/IEC Guide 2, the VIM, and the VIML apply.

B.3.4 Certification body [4], {2.5}

The certification body is the “issuing authority” that reviews and transmits a test report under a declaration of mutual confidence.

B.3.4.1 General provisions [4.1], {3.1}

The policies and provisions of the body shall be nondiscriminatory and shall provide the same level of access to all customers. The procedures for evaluating instruments shall be as given in the relevant OIML Recommendation and any other documented additional requirements.

B.3.4.2 Organization [4.2]

An organizational chart with the description of the responsibilities and functions of all sub-units of the body shall be publicly available.

B.3.4.3 Operations [4.3], {1.1}

The body shall take all necessary steps to evaluate the conformity of measuring instruments to the metrological requirements of the relevant OIML Recommendation and

of any other additional requirements accepted by the Committee on Participation Review, against which the customer wants his instrument to be evaluated.

B.3.4.4 Subcontracting [4.4], {1.1, 3.3.1, 3.5.1}

A body may subcontract work related to the examination and testing of an instrument but shall not delegate its final decision, or judgement, to approve or not to approve an instrument based on the report of the type evaluation. It shall take full responsibility for such work and shall carry out the necessary assessments to ensure the competence of a subcontractor. An customer for type evaluation testing shall be informed of the details regarding any subcontractor involved.

B.3.4.5 Quality system [4.5]

The body shall operate a documented quality system.

B.3.4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification [4.6], {6.7 – 6.9}

The body shall specify and document the conditions and procedures for granting, maintaining, extending, suspending and withdrawing a certification.

B.3.4.7 Internal audits and management reviews [4.7]

The body shall conduct periodic internal audits and management reviews at defined intervals sufficiently short to ensure its continuing suitability and effectiveness and shall take any necessary corrective actions in a timely manner.

B.3.4.8 Documentation [4.8]

The body shall have available current information about the following: the authority to operate; certification rules and procedures; evaluation procedures; fees charged for evaluations and certifications and financial support received; the rights and duties of customers (manufacturers or suppliers); procedures for appealing decisions including the handling of complaints, appeals and disputes; and a directory of measuring instruments types that have been certified including their manufacturers or suppliers.

B.3.4.9 Records [4.9]

The body shall establish and maintain procedures for identifying, filing, accessing, and disseminating test reports and certificates of conformity issued. Records shall be kept for at least 10 years.

B.3.4.10 Confidentiality [4.10]

The body shall have means to safeguard confidentiality of the information obtained in the course of its certification activities.

B.3.5 Certification body personnel [5]

B.3.5.1 General [5.1]

The body shall have competent personnel for carrying out their assigned functions, including making the required legal metrology judgements.

B.3.5.2 Qualification criteria [5.2]

The body shall have defined criteria for assessing the competence of its and contracted personnel involved in the type evaluation and certification process. All personnel involved shall follow defined rules including those relating to the confidentiality and independence from commercial or other interests.

B.3.6 Changes in the issuing authority's certification requirements [6]

The body shall give public notice of any intended changes in its certification requirements and shall provide any views expressed by interested parties to those responsible for consideration before changes are implemented.

B.3.7 Appeals, complaints and disputes [7], {6.2}

The body shall have procedures for addressing appeals, complaints and disputes brought about by suppliers or other parties and shall document any subsequent actions and their effectiveness.

B.3.8 Application for certification [8] {3}

B.3.8.1 Information on the procedure [8.1]

The body shall provide customers up-to-date information regarding procedures and shall require the manufacturer of the measuring instruments to follow the body's rules in the applicable procedures.

B.3.8.2 The application [8.2], {3.1.1}

The body shall require an official application form to be completed by a duly authorized representative of the customer.

B.3.9 Preparation for evaluation [9], {3.2}

The body shall review the application prior to a type evaluation to ensure that the requirements are understood, that any differences in understanding are resolved, and that it has the capability of performing the requested evaluation.

B.3.10 Evaluation [10], {A.1}

The body shall identify the designated testing laboratories in which the specimen or specimens of the measuring instrument type is to be evaluated.

B.3.11 Report of the evaluation [11], {3.4}

The designated testing laboratory shall deliver to the body a report on the findings of the evaluation that is prepared in accordance with the format contained in the applicable OIML Recommendation and any other applicable documents, and the body shall in turn promptly inform the customer.

B.3.12 Decision on certification [12], {3.5.1}

The body shall make a decision, or judgement, to review and transmit a test report and, if requested, to issue a certificate of conformity of a measuring instrument type based on a review of the test report regarding the information gathered during evaluation and testing and any other relevant information.

B.3.13 Surveillance (Supervision of testing laboratories; 8.2)

The body shall have documented procedures to enable surveillance of evaluations carried out, and it shall document the results of its surveillance activities.

B.3.14 Use of licenses, certificates and marks of conformity [14], {5}

The body shall control the ownership, use, and display of its certificates.

B.3.15 Complaints to manufacturers or suppliers [15]

The body shall require the manufacturer or supplier to keep a record of all complaints received with regard to the compliance of a certified instrument with requirements and to document and inform the body of any action taken with respect to such complaints.

ANNEX C

General Format:

Questionnaire on “National Capabilities for Type Testing” (to be completed by potential applicants according to 4.4(a))

DECLARATION OF MUTUAL CONFIDENCE Reference:

OIML Recommendation: _____

Category of Measuring Instruments (including accuracy classes, measuring ranges, etc.):

C.1 STATE: _____

C.2 ISSUING AUTHORITY (Organization/Department)

C.3 ADDRESS _____

C.4 CONTACT (or RESPONSIBLE) PERSON _____

TEL: _____ FAX: _____ E-MAIL: _____

C.5 Do you have national legislation (or national requirements) for this category of measuring instruments?

Yes _____ No _____

If “No”, proceed to C.8.

C.6 Is your organization responsible for both type evaluation and type approval?

Yes _____ No _____

C.7 If the answer to C.6 is No, please identify the organization/department responsible for type evaluation:

C.8 Identify the principal testing laboratory, including any necessary specialized laboratories, involved in type evaluation for this category of instruments in your country and indicate whether the laboratory is a specialized, subcontract laboratory.

C.9 How many OIML test reports and/or Certificates have you issued based on this OIML Recommendation? _____

C.10 Are there differences between your national type evaluation requirements and the requirements in the relevant OIML Recommendation? Yes____ No____
If “Yes”, please elaborate:

C.11 Has your testing laboratory or laboratories identified in C.7 been accredited to carry out the applicable type evaluations by an accreditation body? Yes____ No____

C.12 If the response to C.11 is yes, identify the accreditation body and the date assessed?

C.13 Please give a brief general description of the applicable testing facilities:

C.14 Describe any specialized testing facilities required by this Recommendation and utilized for testing the effects of influence factors (intensity, range, capacity, severity, etc.), for example:

a) Electromagnetic immunity

b) Power mains interference

c) Electrostatic discharge

d) Temperature and humidity chambers

C.15 Have your testing laboratory or laboratories identified in C.7 participated in intercomparisons? Yes _____ No _____

If the answer is yes, identify the instruments (or devices), participants, and dates and attach the report on the intercomparisons, if available:

C.16 How many persons are employed full time in each testing laboratory or laboratories identified in C.7? _____

a) Are the responsibilities of the staff documented? Yes _____ No _____

b) Do you provide specialized and periodic training in type testing for your staff?
Yes _____ No _____

C.17 Briefly describe the organization (or provide an organizational chart) of the staff of the laboratory or laboratories:

Responsible person _____

Title _____

Signature _____

Date _____